EXHIBIT 9

OIG-RPT, MED-GUIDE 1990 MED-GUIDE-TB ¶38,215, **OIG Report Concerning Medicaid and Medicare Reimbursement for Drugs.**, (Oct. 03, 1989)
OIG Report Concerning Medicaid and Medicare Reimbursement for Drugs.

Report of the Office of Inspector General (Office of Audit) CIN: A-06-89-00037), Oct. 3, 1989, Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program.

Medicare and Medicaid: Reimbursement for Drugs

Reimbursement for drugs.--
Reproduced below is an OIG Report recommending the continuation of HCFA's requirement for Medicaid programs to discount average wholesale prices for drugs when AWP is used as a limit on reimbursement. The OIG also recommends consideration of a limit other than AWP, or of a limit using a discounted AWP, regarding Medicare payment for drugs under the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360).

See ¶3175, ¶14,723.

At your request, we are providing this management advisory report summarizing information from our ongoing review of Average Wholesale Prices (AWP) used for reimbursing pharmacies participating in the Medicaid program and the new prescription drug program authorized by the Medicare Catastrophic Coverage Act of 1988 (MCCA).

We are pleased to report that in August 1989, the Health Care Financing Administration (HCFA) issued a revision to the *State Medicaid Manual* pointing out the preponderance of evidence demonstrating that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent. The *Manual* issuance provides that, absent valid documentation to the contrary, it will not be acceptable under Medicaid for a state to make reimbursements using AWP without a significant discount.

We fully concur with this pronouncement that the preponderance of evidence shows that AWP is heavily discounted. During 1984, we issued a report entitled: "Changes to the Medicaid Prescription Drug Program Could Save Millions" (ACN: 06-40216) which concluded that, on average, pharmacies buy drugs for 15.9 percent below AWP. Our 1984 report, which focused on the impact of AWP on Medicaid reimbursement, recommended that HCFA revise Medicaid program regulations and include language to preclude the general use of AWP in pharmacy reimbursement. The HCFA has now fully implemented our recommendation.

Our current work shows there has been no change in the level of discounting since our prior audit but there is a much wider base of awareness now that the discounts occur. Our current review of drug purchase data shows that, on average, pharmacies buy drugs for 15.5 percent below AWP. We continue to believe that AWP is not a meaningful payment level and that it should not be used for making reimbursements in either the Medicaid or the new Medicare drug program.

We are recommending that HCFA continue to require state Medicaid agencies to discount AWP when making program reimbursements. For Medicare, we are recommending that HCFA consider using a reimbursement method other than AWP or discounted AWP similar to the Medicaid approach.

Methodology

Our 1984 review included 38 high-volume drug items and covered 2,086 purchases made in Arkansas and 1,383 purchases made in five additional states for a total of 3,469 purchases of the sample drug items. Our data was gathered by visiting pharmacies and reviewing copies of purchase invoices.

Our current review included 55 high volume drug products, most of which are frequently used by the elderly. We relied on pricing information gathered from four different sources. The primary source of our

pricing information came from one of the nation's largest drug wholesalers. We visited the wholesaler and reviewed 4,389 pharmacy invoices for May 1989 covering Texas and Louisiana. A representative for the wholesaler confirmed that the same prices were in effect in Kansas, Oklahoma and Nebraska. We also obtained 71 national prices for our sample drug items from that same wholesaler's pricing catalog. Further, we obtained 243 invoice prices for our sample drug items from a study conducted by a CPA firm under contract with the Arkansas State Medicaid agency. Finally, we obtained 20 invoice prices from a study conducted in pharmacies in the State of Louisiana by HCFA's Region VI office. These various sources of pricing information gave us a total 4,723 prices on which to base our estimates.

We obtained our AWP information from national drug pricing authorities including "Blue Book" and "Medi-Span."

In addition to the pricing study, we interviewed the Director of the Texas Medicaid drug program regarding the state's implementation of a policy to discount AWP reimbursement to Medicaid pharmacies.

Results

Our 1984 review showed an average discount below AWP of 15.7 percent in Arkansas and 15.9 percent for five additional states. Our current work shows that there has been insignificant change from the last audit since the overall discount rate is about 15.5 percent.

Our study of prices actually paid by pharmacies for high-volume sample drug items resulted in 3,320 prices for single source items and a weighted average price below AWP of 14.39 percent. For multiple-source drugs, our sample of 1,403 prices showed a weighted average price below AWP of 18.20 percent. The combined rate for both single-source and multiple-source drugs is 15.52 percent.

The following table summarizes the sources of our prices for our current study.

Source	Single Source No. of Prices	Discount Percent	Multiple No. of Prices	Discount Percent From
Wholesaler	3,077	14.47	1,312	17.85
Wholesaler's Catalog	25	13.24	46	31.51
C.P.A.'s--Arkansas	200	13.34	43	14.70
HCFA--Louisiana	18	14.15	2	17.27
Totals	3,320	14.39	1,403	18.20

As shown above, we obtained the pricing information for our current study primarily from drug wholesalers, rather than from pharmacies. We contacted four of the Nation's largest wholesalers and inquired about their actual selling prices to pharmacies. While officials of all four wholesalers acknowledged that drugs are sold to pharmacies at discounts below AWP, only one of the wholesalers would agree to show us their actual pharmacy invoices. However, the other three wholesalers made the following comments to us with regard to AWP:

Wholesaler A: "Overall selling price would be about 12 percent off AWP."

Wholesaler B: "AWP is a meaningless figure."

"Most of . . . pricing is based on cost plus a percentage markup."

"This computed selling price would be less than the AWP."

Wholesaler C: ". . . it is recognized in the industry that there are discounts off AWP . . . selling price is based on AWP less a discount or . . . cost plus a markup."

The only significant change since our prior audit is that all facets of the industry are willing to admit that the discounts exist. For example, consider the following comments by pharmaceutical officials:

Rugby Laboratories' Director of Regulatory Affairs was recently quoted in the Lexington Herald-Leader as saying: "The (Average Wholesale Price) is a joke . . . it has largely become a farce because many companies have abused it and continue to abuse it."

Also, a top Pennsylvania Medicaid official was quoted in the same publication as saying the average wholesale price: ". . . just doesn't mean anything. It has no connection to what pharmacies really purchase the drug for."

There is a growing trend to discount AWP when it is used as a basis for making drug reimbursements. After our 1984 report was issued, the Texas State Medicaid agency changed its reimbursement method to reduce AWP by 10.49 percent, which has saved millions of dollars. The Director of the Texas Medicaid drug program, in a recent interview, advised us that Texas experienced no decline in pharmacy participation when the discount provision was instituted—in fact, participation has since gone up. This official informed us that, in Texas, the Medicaid business represents about 8 to 10 percent of the prescription drug sales in the typical pharmacy and that there are only a handful of high volume Medicaid pharmacies (over 50 percent Medicaid business). Further, this official pointed out that, since drug stores sell many sundry items besides drugs, the impact on total sales resulting from discounting AWP on Medicaid prescriptions was very small—too small to adversely affect pharmacy participation in the program.

The Texas Director explained that sometimes pharmacists benefit from filling prescriptions, even at no profit, because it provided a broader base over which to spread overhead costs. He pointed out that about 60 percent of the Medicaid prescriptions are filled with generic drugs. That was advantageous to the pharmacist because generic drugs can be purchased at a greater discount than brand name drugs and the discounted AWP has less impact on generic drugs.

A recent survey conducted by the Texas Medicaid agency of 18 third-party programs in Texas showed that each program used AWP in the reimbursement formula. However, in four of the programs, the AWP was discounted from 10 to 15 percent.

Impact of AWP Discounting on Pharmacies

Medicaid

In our 1984 report, we pointed out that pharmacists were generally paid the lesser of their usual and customary charge to the general public or AWP plus a dispensing fee (or in some cases a specific maximum amount set either by HCFA or the state). Since the discounted AWP would not be used in making every reimbursement, the full 15.9 percent discount would not be realized as Medicaid savings. We estimated that only about 11 percent of the program reimbursement could be saved via discounting AWP.

Since that time, the Medicaid regulations have been revised with different payment methods now applying depending on whether single-source or multiple-source drugs are involved. The discounting of AWP now only affects reimbursements for single-source drugs and then only in those instances when that amount is less than the pharmacy's usual and customary charge to the public.

Medicare

The outpatient prescription drug portion of the Medicare Catastrophic Coverage Act is scheduled to become operational in January 1991. The MCCA legislation calls for the use of non-discounted AWP, plus an administrative allowance, as one of the reimbursement limits for prescription drugs. It should be noted that, during the period beneficiaries are paying their deductible amounts, no program reimbursements are involved and the pharmacists are supposed to charge usual and customary amounts. After the beneficiaries' deductible has been met, the program reimbursement method would vary depending on whether single-source or multiple-source drugs are involved.

For single-source drugs, reimbursement would be limited to the lesser of the pharmacy's usual and customary charge to the general public, the 90th percentile of usual and customary charges for a geographic area, or AWP plus an administrative allowance. For multiple-source drugs, the reimbursement would be limited to the lesser of the pharmacy's usual and customary charge or the unweighted median of the AWP on a national basis plus an administrative allowance. Since AWP would be used for only some of the reimbursements, the discounting of AWP for Medicare would have less than the full effect of the discounts. At this time, there is no information available regarding the frequency that each of the payment methods will be used in making reimbursements. However, since both multiple-source and single-source drugs have a method that involves AWP, we believe that the impact of discounting AWP would be somewhat greater for Medicare than for Medicaid. The impact on a drug store's sales should be fairly small.

Conclusions and Recommendations

We conclude that there has been little change in the practice of discounting AWP since our prior audit. Based on our work then and our current ongoing efforts, we continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare programs. When AWP is used, we believe that it should be discounted.

We recommend that HCFA continue current policy in the Medicaid program which requires State agencies to discount AWP when making program reimbursements. For the new Medicare prescription drug program, we recommend that alternate reimbursement methods be studied and that consideration be given to using a reimbursement method other than AWP or permit AWP to be appropriately discounted for reimbursement purposes. Our ongoing work is exploring methods of reimbursement other than AWP.

MED-MANUAL. §6305.1 Upper Limits Requirements.
§6305.1 Upper Limits Requirements..
State Medicaid Manual, Part 6 (CMS-Pub. 45-6)

A. Multiple Source Drugs--

1. Definition.--A multiple source drug is a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

2. Establishment of Limit Under 42 CFR 447.332.--Under the authority of §1902(a)(30)(A) and the regulations in 42 CFR 447.332, HCFA establishes a specific upper limit for a multiple source drug if the following requirements are met:

- All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the current edition of the publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or successor publications); and

- At least three suppliers list the drug in the current editions (or updates) of published compendia of cost information for drugs available for sale nationally (e.g., Red Book, Blue Book, Medi-Span.)

3. Application of New Limits Under §1927(f)(2).--Under the authority of §1927(f)(2), HCFA establishes listings that identify and set upper limits for multiple source drugs for which at least three of the formulations of the drug approved by the FDA have been evaluated as therapeutically and pharmaceutically equivalent (category A) in the most current edition of its publication Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications) regardless of whether all additional formulations are rated as such.

4. Application of Limits Under 42 CFR 447.332 and §1927(f).--The agency's payment for multiple source drugs identified and listed in Addendum A must not exceed, in the aggregate, payment levels determined by applying to each drug entity a reasonable dispensing fee, (established by the State and specified in the State Plan), plus an amount based on the limit per unit which HCFA has determined to be equal to a 150 percent applied to the lowest price listed (in package sizes of 100 units, unless otherwise noted) in any of the published compendia of cost information of drugs.

The upper limit for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient. The handwritten phrase "brand necessary" or "brand medically necessary" must appear on the face of the prescription. A dual line prescription form does not satisfy the certification requirement. A checkoff box on a form is not acceptable, but, again a notification like "brand necessary" is allowable. For telephone prescriptions, decide what certification form and procedures are to be used. Providers may be allowed to keep the certification forms if the forms are available for inspection by their agency and HHS.

In accordance with current policy, Federal financial participation will not be provided for any drug on the FUL listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the Drug Efficacy Study and Implementation (DESI) program and the drug has been found to be a less than effective or is identical, related or similar (IRS) to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the Medicaid drug rebate program.

B. Other Drugs.--A drug described as an "other drug" is a brand name drug certified as medically necessary by a physician or a drug other than a multiple source drug (See §6305.1.A.). Payments for these drugs must not exceed, in the aggregate, payment levels determined by applying the lower of the:

- Estimated acquisition costs, plus reasonable dispensing fees (established by the State and specified

in the State Plan), or

- The provider's usual and customary charges to the general public.

Estimated acquisition costs (EAC) means the agency's best estimate of the price generally, and currently, paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers. For example, in the past, many States based the EAC upon Average Wholesale Price (AWP) levels as contained in various commercially available publications. However, a number of studies have shown that in recent years the drug marketplace has changed and there is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, without valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers.